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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	5171-00041	2358

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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/023,437		JOHNSTON ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Vanessa L. Ford		1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-27, 29-39, 41-45, 50-61, 74, 76-81, 83 and 92-115 is/are pending in the application.
- 4a) Of the above claim(s) 26, 27, 29-38, 50-61 and 76-81 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 92, 104, 107, 110 and 113 is/are allowed.
- 6) ☒ Claim(s) 25, 39, 41-45, 74, 83 and 96-103 is/are rejected.
- 7) ☒ Claim(s) 94, 95, 105, 106, 108, 109, 111, 112, 114 and 115 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2005 has been entered. Claims 25, 39, 41-42 and 83 have been amended. Claims 1-24, 28, 40, 46-49, 63-73, 75, 82 and 84-91 have been cancelled. Claims 92-107 have been added. Claims 26-38, 50-61 and 76-81 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It should be noted that the amino acid sequences examined in this application are SEQ ID NOs: 7, 9, 11 and 13 as they relate to the claimed invention. No new species of SEQ ID NOs. are examined.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

### ***Rejection Maintained***

3. The rejection under 35 U.S.C. 112, first paragraph is maintained for 25, 39, 41-45, 74, 83 and newly submitted claims 96-103 for the reasons set forth on pages 2-7, paragraph 4 of the Final Office Action.

The rejection was on the grounds that the claims while being enabling for a method of immunizing an animal comprising providing to the animal; at least one

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*Chlamydia* antigen corresponding to SEQ ID No. 9 or SEQ ID No. 7 and further comprising a second *Chlamydia* antigen corresponding to SEQ ID No. 11 or SEQ ID No. 13 does not reasonably provide enablement for all antigenic fragments of the SEQ ID Nos. 7, 9, 11 or 13 encompassed by the claims that can be used in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches that the term "fragment" is defined as a sequence having at least 5 or more contiguous residues but less than the full-length of the SEQ ID Nos. (page 13). The specification teaches that it is contemplated that the definition of "fragment" can be applied to amino acid as well as nucleic acid fragments (page 13). The specification refers to the "antigenic fragment" as a fragment that can elicit an immune response in an animal (page 13).

The specification has failed to provide a structure for all of the antigenic fragments encompassed by the claimed invention.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the protein's structure relates to function. However, the problem of the prediction of protein's structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polynucleotide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications. The sequence of some proteins is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such protein.

Thomas E. Creighton, in his book, *"Proteins: Structures and Molecular Properties, 1984"*, (page 315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a proline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

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Thomas E. Creighton, in his book *"Protein Structure: A Practical Approach, 1989; pages 184-186"* teaches that present day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions". The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in *"Protein Stability and Stabilization through Protein Engineering, 1991"* (chapter 7, page 197, second paragraph) adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

There is no guidance provided in the specification as how one would begin to choose all "antigenic fragments" of SEQ ID NOs. 7, 9, 11 or 13 encompassed by the claims. The specification does not support the broad scope of the claims, which encompass all modifications and fragments because the specification does not disclose the following:

- the general tolerance to modification and extent of such tolerance;
- specific positions and regions of sequence(s) which can be predictably modified and which regions are critical;
- what fragments, if any, can be made which the retain the biological activity if the intact protein; and
- the specification provide essentially no guidance as to which of the essentially infinite possible choice is likely to be successful.

Factors to be considered in determining whether undue experimentation is required are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other proteins having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use proteins all antigenic fragments of SEQ ID Nos. SEQ ID Nos. 7, 9, 11 or 13 in manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

The Applicant has not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of deletions or substitutions and fragments of any size. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made in the amino acid's structure and still maintain activity is unpredictable and the experimentation left those skilled in the art is

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unnecessarily and improperly, extensive and undue. See *Amgen Inc v Chugai Pharmaceutical Co Ltd.* 927 F 2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and *Exparte Forman*, 230 U.S. P.Q. 546(Bd. Pat. App & int. 1986).

#### Applicant's Arguments

A) Applicant disagrees with the Examiner's position that the instant specification is not enabling for fragments of SEQ ID NOs: 7, 9, 11 and 13. Applicant urges that they have amended independent claim 25 to a method of immunizing an animal comprising administering a *Chlamydia psittaci* antigen having the amino acid sequence as set forth in SEQ ID NO:7.

B) Applicant urges that claim 92 includes recitation of an antigenic structure as well as recitation of additional active steps of the claimed methods.

#### Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 31, 2005 have been fully considered but they are not persuasive.

A) It is the Examiner's position that claims 25, 39, 41-45, 74, 83 and 96-103 are not limited to polypeptides that comprise SEQ ID NO:7, 9, 11 or 13. The claims as amended read on sequences that are less than the full-length of SEQ ID Nos. 7, 9, 11 and 13 (e.g. fragments of SEQ ID NOs: 7, 9, 11 and 13). The instant specification is not enabled for methods of immunizing animals comprising the administration of variants or fragments of SEQ ID NOs: 7, 9, 11 and 13. It should be remembered that the statute under 35 U.S.C. 112, first paragraph requires that the specification teach how to make

and use polypeptides of the claimed invention not how to “find” variants or fragments of the *Chlamydia* polypeptides (e.g. SEQ ID NOs. 7, 9, 11 and 13) used in the claimed method. A structure is required for the polypeptides used in the claimed method. It should be remembered while recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide’s sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure.

B) While independent claim 92 is directed to a method of immunizing an animal comprising administering *Chlamydia psittaci* antigen comprising the amino acid sequence as set forth in SEQ ID NO.9, dependent claims 96-103 are directed to variants or fragments of SEQ NOs: 7, 9, 11 and 13 and these fragments are not enabled by the instant disclosure. Applicant has not shown how to “make and use” fragments of SEQ ID NOs:7, 9, 11 and 13. Therefore, Applicant has not met their burden as set forth in 35 U.S.C. 112, first paragraph.

**It should be noted that claims 25, 39, 41-45, 74, 83 and 96-103 are not limited to a polypeptides that comprise SEQ ID NO:7, 9, 11 or 13. Claims read on variants or fragments of SEQ ID NOs:7, 9, 11 and 13. Therefore, the following art rejections are maintained.**

4. The rejection under 35 U.S.C. 102(e) is maintained for 25, 39, 41-45, 74, 83 and newly submitted claims 100-103 for the reasons set forth on pages 8-9, paragraph 6 of the Final Office Action.

The rejection was on the grounds that Griffais et al teach a method of immunizing an animal comprising administering vaccine compositions comprising at least one *Chlamydia* antigen or antigenic fragment in an amount to induce an immune response (columns 62-64). Graffais et al teach that the vaccine composition are administered to a mammalian host (column 62) including humans (column 63). Griffais et al teach that any number of antigens may be included in the invention (see Table 1). Griffais et al teach that antigen from *Chlamydia psittaci* may be included in the invention. Therefore, the prior art meets the claim limitation "...wherein the method is effective to induce an immune response against *Chlamydia psittaci*". The prior art teaches antigenic fragments of SEQ ID Nos. 7 and 9 (corresponding to the first *Chlamydia* antigen) as well as antigenic fragments of SEQ ID Nos. 13 (corresponding to the second *Chlamydia* antigen). SEQ ID NO: 59 of the prior art corresponds to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art corresponds to antigenic fragments of SEQ ID NO:13. See the attached sequence alignments.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

#### Applicant's Arguments

A) Applicant urges that Griffais et al do not teach or enable each of the claimed elements of independent claim 25 or 92 either expressly or inherently.

Applicant urges that the present claims are directed to a method of immunizing an animal comprising administering to the animal a *Chlamydia psittaci* antigen having a specific SEQ ID NO. in a effective amount to induce an immune response against *Chlamydia psittaci*. Applicant urges that the claimed subject matter is not placed within the possession Griffais et al.



B) Applicant urges that Griffais et al do not show any expression or teach that the proteins used in the invention as immunogens. Applicant urges that even if the genes are homologues, there is not basis for making the conclusion that certain gene would provide the same type of immune protection. Applicant urges that Graffais et al do not teach functional characterizations of any gene for functional efficacy it simply list sequences.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 31, 2005 have been fully considered but they are not persuasive.

A) The claims are directed to a method of immunizing an animal comprising preparing and administering *Chlamydia psittaci* antigen "having a sequence of either SEQ ID NOs:7, 9, 11 or 13". The claims are not limited to polypeptides that comprise SEQ ID NO:7, 9, 11 or 13. These claims read on sequences that are less than the full-length of SEQ ID Nos. 7, 9, 11 and 13 (e.g. fragments of SEQ ID NOs: 7, 9, 11 and 13). Graffais et al disclose amino acid sequences that are fragments. The prior art teach that SEQ ID NO: 59 of the prior art corresponds to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art corresponds to antigenic fragments of SEQ ID NOs:11 and 13. Applicant has provided no side-by-side comparison to show that the method of the prior art is not the same as the claimed method.

B) To address Applicant's comment regarding the protein of the prior art being immunogenic, it should be noted that Graffais et al teach that the polypeptides, proteins or fusion proteins can be used may be used as immunogens to generate

antibodies or other derivatives or analogs thereof (column 54). It should be noted that Graffais et al teach that the polypeptides of the invention can be used in pharmaceutical compositions, immunogenic compositions and vaccine compositions (columns 61-62). It should be further noted that Graffais et al teach the administration of the polypeptides of the invention to animals to elicit immune responses (columns 63-64).

To address Applicant's comment regarding the polypeptides encompassed by the claimed invention and functional characterization, it should be noted that Applicant's invention encompasses variants and fragments of SEQ ID NOs:7, 9, 11 or 13 and it is well known in the art that all variants and/or fragments of a protein or polypeptide may not possess the functional characteristics of the reference polypeptide. For example, Thomas E. Creighton, in his book, *"Proteins: Structures and Molecular Properties, 1984"*, (page 315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a proline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

There is nothing of record to suggests that the method of the prior art differs from that of the claimed invention. Thus, Graffais et al anticipate the claimed invention.

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5. The rejection under 35 U.S.C. 102(b), is maintained for 25, 39, 41-45, 74, 83 and newly submitted claims 100-103 for the reasons set forth on pages 10-11, paragraph 7 of the Final Office Action.

The rejection was on the grounds that Griffais teaches a method of immunizing an animal comprising administering vaccine compositions comprising at least one *Chlamydia* antigen or antigenic fragment in an amount to induce an immune response (page 71-73). Griffais teaches that the vaccine composition are administered to a mammalian host including humans (pages 72-73). Griffais teaches that any number of antigens may be included in the invention (see Table 1). Griffais teaches that antigen from *Chlamydia psittaci* may be included in the invention. Therefore, the prior art meets the claim limitation "...wherein the method is effective to induce an immune response against *Chlamydia psittaci*". The prior art teaches antigenic fragments of SEQ ID Nos. 7 and 9 (corresponding to the first *Chlamydia* antigen) as well as antigenic fragments of SEQ ID Nos. 13 (corresponding to the second *Chlamydia* antigen). SEQ ID NO: 59 of the prior art correspond to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art correspond to fragments of SEQ ID NO:13. See the attached sequence alignments.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

#### Applicant's Arguments

A) Applicant urges that Griffais does not teach or enable each of the claimed elements of independent claim 25 or 92 either expressly or inherently. Applicant urges that the present claims are directed to a method of immunizing an animal comprising administering to the animal a *Chlamydia psittaci* antigen having a specific SEQ ID NO. in a effective amount to induce an immune response against *Chlamydia psittaci*. Applicant urges that the claimed subject matter is not placed within the possession Griffais.

B) Applicant urges that Griffais et al do not show any expression or teach that the proteins used in the invention as immunogens. Applicant urges that even if the genes are homologues, there is not basis for making the conclusion that certain gene would provide the same type of immune protection. Applicant urges that Graffais does not teach functional characterizations of any gene for functional efficacy it simply list sequences.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 31, 2005 have been fully considered but they are not persuasive.

A) The claims are directed to a method of immunizing an animal comprising preparing and administering *Chlamydia psittaci* antigen "having a sequence of either SEQ ID NOs:7, 9, 11 or 13". The claims are not limited to polypeptides that comprise SEQ ID NO:7, 9, 11 or 13. These claims read on sequences that are less than the full-length of SEQ ID Nos. 7, 9, 11 and 13 (e.g. fragments of SEQ ID NOs: 7, 9, 11 and 13). Graffais discloses amino acid sequences that are fragments. The prior art teach that SEQ ID NO: 59 of the prior art corresponds to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art corresponds to antigenic fragments of SEQ ID NOs:11 and 13. Applicant has provided no side-by-side comparison to show that the method of the prior art is not the same as the claimed method.

B) To address Applicant's comment regarding the protein of the prior art being immunogenic, it should be noted that Graffais teaches that the polypeptides of the invention can be used in pharmaceutical compositions, immunogenic compositions and vaccine compositions (pages 70-72). It should be further noted that Graffais teaches

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the administration of the polypeptides of the invention to animals to elicit immune responses (pages 72-73).

To address Applicant's comment regarding the polypeptides encompassed by the claimed invention and functional characterization, it should be noted that Applicant's invention encompasses variants and fragments of SEQ ID NOs:7, 9, 11 or 13 and it is well known in the art that all variants and/or fragments of a protein or polypeptide may not possess the functional characteristics of the reference polypeptide. For example, Thomas E. Creighton, in his book, *"Proteins: Structures and Molecular Properties, 1984"*, (page 315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a proline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

There is nothing of record to suggests that the method of the prior art differs from that of the claimed invention. Thus, Graffais et al anticipate the claimed invention.

***New Ground of Rejection***

6. Claims 94-103, 105-106, 108-109, 111-112 and 114-115 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

***Status of Claims***

7. Claims 92-99 are free of cited prior art. Claims 92-93, 104, 107, 110 and 113 are allowed.

***Conclusion***

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
January 11, 2006

  
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